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UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re:	**Chapter 11**
PURDUE PHARMA L.P., *et al.*,	**Case No. 19-23649 (RDD)**
Debtors.[1]	**(Jointly Administered)**

DECLARATION OF JON LOWNE IN SUPPORT OF DEBTORS' MOTION FOR AUTHORIZATION TO ENTER INTO FUNDING AGREEMENT

I, Jon Lowne, being fully sworn, hereby declare that the following is true to the best of my knowledge, information and belief:

[1] The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF LP (0495), SVC Pharma LP (5717) and SVC Pharma Inc. (4014). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

1. I am the Chief Financial Officer of Purdue Pharma L.P. ("**PPLP**" and, collectively with each of the other above-captioned debtors, the "**Debtors**," the "**Company**" or "**Purdue**"). I was first employed by Purdue as Senior Internal Auditor in 1995 and gained increasing responsibility in the Company's finance team over time, including as Controller from 2005 to July 2017, and then as Acting Chief Financial Officer from August 2017 to February 2018. Since March 2018, I have been the Chief Financial Officer of PPLP. I am familiar with the day-to-day operations, business and financial affairs of the Debtors

2. I make this declaration (the "**Declaration**") in support of the *Motion of Debtors for Authorization to Enter into Funding Agreement* (the "**Motion**"). All capitalized terms used but not defined herein have the meanings ascribed to them in the Motion.

3. Except as otherwise indicated, all facts set forth in this Declaration are based upon my personal knowledge, my review of relevant documents, information provided to me by employees working under my supervision, or my opinion based upon experience, knowledge and information concerning the operations of the Debtors and the pharmaceutical industry as a whole. If called upon to testify, I would testify competently to the facts set forth in this Declaration.

There Is an Urgent Need for Low-Cost Over-the-Counter Naloxone Rescue Drug Products

4. The Centers for Disease Control and Prevention estimates that, every day, 130 Americans die from opioid overdose.[2] More of these deaths could be prevented if individuals, families, first responders and communities had greater access to naloxone, an opioid antagonist medication that can safely and effectively counter the effects of an opioid overdose. In intranasal form, naloxone can be administered by the general public with limited-to-no training. The Food and Drug Administration (the "**FDA**") supports efforts to increase the availability of naloxone

[2] Centers for Disease Control and Prevention, Understanding the Epidemic, https://www.cdc.gov/drugoverdose/epidemic/index.html.

medications and has publicly expressed its belief that the improved access to safe, effective and easy-to-use naloxone rescue drug devices is critical to reducing opioid overdose-related deaths.[3]

5. Naloxone is currently available only by prescription. The lack of an over-the-counter ("**OTC**") product results in two fundamental barriers to increasing availability: cost and access. The cost of prescription naloxone medications is a significant impediment to wider distribution, especially in communities hardest hit by the opioid crisis.[4] In addition, OTC availability has the potential to dramatically improve access. Individuals are often unable or unwilling to go through the process of visiting a doctor and navigating their insurance coverage in order to obtain a prescription for naloxone that then must be filled by a pharmacist. Many (but not all) states have attempted to address this concern by either issuing statewide orders enabling the sale of naloxone without a prescription or authorizing jurisdictions to pass naloxone standing order laws.[5] However, even these measures are imperfect and impose barriers to access.[6] OTC naloxone, by contrast, would not involve doctors, pharmacists, or insurance companies and would require minimal to no touch points (OTC products may be purchased online in many cases).

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[3] *See* U.S. Food and Drug Admin., FDA Statement, Statement on Continued Efforts to Increase Availability of All Forms of Naloxone to Help Reduce Opioid Overdose Deaths (Sept. 20, 2019), https://www.fda.gov/news-events/press-announcements/statement-continued-efforts-increase-availability-all-forms-naloxone-help-reduce-opioid-overdose ("Naloxone is a critical tool for individuals, families, first responders and communities to help reduce opioid overdose deaths.").

[4] *See* Gupta R. et al. *The rising price of naloxone — risks to efforts to stem overdose deaths*, N. Engl. J. Med. 2016; 375:2213-2215, https://www.nejm.org/doi/full/10.1056/NEJMp1609578.

[5] SAFEProject, *State Naloxone Access Rules and Resources*, https://www.safeproject.us/naloxone-awareness-project/state-rules/.

[6] *See* Murphy, Morgan, Jeng and Schackman, *Will converting naloxone to over-the-counter status increase pharmacy sales?*, Health Serv Res. 2019; 54:765.

6. As a result of these barriers, naloxone is being dramatically underprescribed to the American public.[7] One recent study found that making an OTC naloxone product available could result in a "substantial increase" in the number of products distributed, potentially as high as 179%.[8] The study noted this finding was comparable to historical examples of OTC conversions, such as certain smoking cessation medications that experienced increases of up to 180% in the rate of product distribution following OTC conversion.[9]

7. The FDA agrees. In fact, the FDA (in what it describes as an "unprecedented step") completed part of the application itself, specifically label development and comprehension studies, as an incentive for an applicant to bring an OTC naloxone product to market.[10]

8. Purdue is committed to its transformation into a public benefit corporation that will advance meaningful solutions to the opioid crisis and save lives. Breaking down the twin barriers to availability of life-saving naloxone medications in an easy-to-use intranasal form—cost and access—is a core component of this initiative.

HRT's Team Has a Strong Record of OTC Conversions

9. Purdue is facilitating the development of a low-cost OTC naloxone nasal spray device (the "**Product**") by Harm Reduction Therapeutics, Inc. ("**HRT**"). HRT is a nonprofit independent pharmaceutical company organized exclusively for charitable, religious, educational

[7] *See* Lin, L., Brummett, C.M., Waljee, J.F. et al., Association of Opioid Overdose Risk Factors and Naloxone Prescribing in US Adults, J. Gen. Intern. Med. 35, 420–427 (2020), https://doi.org/10.1007/s11606-019-05423-7 (concluding with respect to naloxone prescriptions that, "overall prescribing remains minimal. Additional efforts are needed across health systems to increase naloxone prescribing for patients at risk for opioid overdose.").

[8] *See* Murphy et al., *supra* note 6, at 54:764–772.

[9] *Id*. at 767.

[10] *Id.*

and scientific purposes. HRT was founded in 2017 with a mission to save lives by making the Product available over-the-counter at low cost.

10. HRT's management team has a long and successful history transitioning prescription medications to OTC. Members of the management team have helped develop OTC versions of products such as Nicorette®, Plan B®, Nasacort® Allergy, NicoDerm® CQ®, Prilosec OTC® and Allegra®, among others. Members of the team also have deep expertise in addiction research and substance abuse treatment.

HRT Is Well Positioned to Continue Developing the Product

11. The Debtors began supporting HRT in its development of an OTC naloxone nasal spray in 2018. In September 2018, PPLP made a $3.42 million unrestricted grant to HRT to support development. Purdue agreed to fund an additional $2.5 million for further development of the Product in November 2019. In return, HRT affirmed its commitment to manufacture millions of units of the Product so that such units can be donated free-of-charge or sold at Cost (as defined in the Agreement).

12. The funding and other support from Purdue has enabled HRT to make significant and encouraging progress in the Product's development. This progress includes, among other things, HRT's development of the intranasal naloxone delivery device, Product formulation, participation in a Pre-Investigational New Drug Meeting with the FDA, submission of the Product's name for the FDA's review, and establishment and identification of advisory boards and vendors. HRT has also begun Chemistry, Manufacturing, and Control ("**CMC**") and formulation work, commenced final biocompatibility and other studies, and begun to prepare the Product's New Drug Application ("**NDA**"). In practical terms, HRT is well positioned for final FDA review and approval of the Product by the end of 2021.

13. However, as anticipated, HRT requires additional funding to complete the Product's development and FDA approval phase. By this Motion, the Debtors seek authorization to enter into a Funding Agreement (the "**Agreement**") between PPLP and HRT to fund the continuation of HRT's development work with the goal of obtaining regulatory approval for the Product.

14. The Debtors believe that HRT is well positioned to partner with Purdue to complete development of the Product because HRT has:

- a strong and experienced leadership and scientific team;
- a history of effective collaboration with the Debtors' senior management and scientists;
- a known and established intranasal device;
- a proprietary preservative-free 3 mg naloxone formulation well suited to intranasal delivery;
- an identified contract manufacturer and sales and distribution vendor;
- established scientific and commercial advisory boards; and
- a strong position to obtain FDA fast-track designation for the Product.

The Agreement

15. The Agreement provides that the Debtors will fund $11.5 million for HRT to continue Product development in 2020–21, with each advance subject to HRT meeting certain development milestones (the "**Milestones**"). The Milestones are:

- $2.5 million upon the start of Scale-Up Batch at an identified, well-established contract manufacturer (which indicates progress towards formulation development, establishing the Product's stability and further clinical study);
- $4 million upon the start of Phase 1 Study First Patient In (when testing of the Product with patients begins); and

- $5 million upon the completion of Phase 1 Study's Clinical Study Report (which indicates that certain data that is critical to filing an NDA has been collected and provided in the report).

16. These Milestones are projected to be achieved by May 2020, August 2020 and December 2020, respectively, and payments are not due until shortly after the specified events occur. The Debtors and HRT expect that the Agreement will fully fund research and development for the Product, including all clinical studies, through the NDA filing, which is anticipated to be made in the beginning of 2021, based on current information. The Agreement further provides for the Debtors to continue to provide support and assistance in the Product's development. The Agreement further contemplates that, subject to FDA approval of the Product, PPLP intends (but is not obligated) to provide funds to HRT to enable HRT to manufacture up to approximately 14.6 million units of the Product through 2029 so that such units can be donated free-of-charge or sold at Cost.

17. The Debtors hope that millions of doses of the Product will be distributed to communities around the country at low or no cost and believe that the availability of the Product in the United States would save thousands of lives per year. However, under the terms of the Agreement, the Debtors have no obligation to conduct any commercialization activities or purchase any Product. The maximum total costs that the Debtors are obligated to incur under the Agreement are limited to $11.5 million in Milestone payments plus the costs of certain of the Debtors' employees providing assistance to HRT during the development process.

18. The negotiation of the terms of the Agreement was conducted at arm's length. The terms of the Agreement have been reviewed, and entry into the agreement approved, by the independent Special Committee of PPLP's Board of Directors.

Conclusion

19. Upon the Debtors' careful consideration of the Agreement, including the benefits and risks attendant thereto, I believe that continuing to fund HRT's development work in connection with the Product pursuant to the terms of the Agreement is in the best interests of all stakeholders in these Chapter 11 Cases and the American public.

20. Therefore, I believe that the relief requested in the Motion is in the best interests of the Debtors' estates, creditors and all parties in interest.

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Dated: April 1, 2020
New York, New York

By: */s/ Jon Lowne*
Jon Lowne
Chief Financial Officer
Purdue Pharma L.P.